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March 16, 2018

Dockets Management Staff (HFA–305),
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6502—Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation; Request for Comments

To Whom It May Concern:

On behalf of our 161,000 dentist members, we are pleased to respond to the Food and Drug Administration's (FDA) request for information on questions relevant to FDA's Opioid Policy Steering Committee (OPSC). We offer these comments in response to your Federal Register notice of December 13, 2017 (82 FR 58572).

The FDA established the OPSC to make recommendations about how the agency can use its resources and authorities to reduce cases of overdose, misuse, and abuse of opioid pain relievers. The OPSC is currently seeking input about how FDA might leverage its Risk Evaluation and Mitigation Strategy (REMS) authorities to:

- Require some form of mandatory education for health care professionals who prescribe opioid drug products.
- Require opioid prescribers to adhere to additional protocols when prescribing a quantity above a specified amount (e.g., furnishing medical necessity documentation, etc.).
- Require covered drug companies to create a national prescription drug monitoring database for real-time identification of doctor shopping and harmful drug combinations.
- Require covered drug companies to create a vehicle for patients to dispose of unused pills.

Enclosed you will find our detailed comments about how the FDA might leverage its REMS authorities to promote more judicious opioid prescribing. We recommend that the FDA use its REMS authorities to:

- Require covered drug manufacturers to offer free continuing education that is acceptable for both DEA registration and state licensure purposes.
- Tailor the educational content to the practitioner's scope of practice and the nature of the type of pain managed (e.g., chronic vs. acute pain, dental pain vs. medical pain, etc.).

- Require covered drug companies to enter a cooperative venture to develop effective PDMP quality measures and make state PDMPs interoperable.

- Require covered drug manufactures and/or pharmacies develop convenient ways for patients to safely secure, monitor and dispose of unused medications.

These recommendations are consistent with our comments of July 17, 2017, regarding revisions to FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids.[1]

We are pleased that FDA is revisiting its risk management program to ensure opioid prescribing is better tailored to the medical indication. We would welcome the opportunity to work with you on a risk management program that addresses the nuances of managing acute pain in dental settings.

Thank you for providing us the opportunity to comment. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org. Information is also available at ADA.org/opioids.

Sincerely,

/s/

Joseph P. Crowley, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

JPC:KTO:rjb
Enclosure

[1] Gary L. Roberts and Kathleen T. O'Loughlin, American Dental Association, letter to Food and Drug Administration, July 17, 2017.

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DETAILED COMMENTS
March 16, 2018

Food and Drug Administration Docket No. FDA-2017-N-6502

Opioid Policy Steering Committee: Prescribing Intervention—
Exploring a Strategy for Implementation; Request for Comments

The American Dental Association (ADA) is pleased to offer these detailed comments in response to the Food and Drug Administration's (FDA) Federal Register notice of December 13, 2017 (82 FR 58572).

In 2007, FDA was given the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers of certain medications with serious safety concerns. A REMS may include one or more elements, depending on the safety risk posed by the covered drug. For example, a REMS may require that the drug packaging include a medication guide, or that the drug be dispensed only in certain settings, or that prescribers have particular training or experience, etc.

The FDA established an Opioid Policy Steering Committee to make recommendations about how the agency can use its resources and authorities to reduce cases of overdose, misuse, and abuse of opioid pain relievers. The OPSC is currently seeking input about how FDA might leverage its Risk Evaluation and Mitigation Strategy (REMS) to address the following questions.

1. **Should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?**

The ADA supports mandatory continuing education for opioid prescribers—with an emphasis on preventing drug overdoses, chemical dependency, and drug diversion—and we would welcome low and no-cost opportunities for dentists to refresh their knowledge about managing acute dental pain.

Unfortunately, the FDA's current Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioids is not particularly relevant to the practice of dentistry.

The FDA's current opioid REMS requires covered drug manufacturers to offer low or no cost educational content covering the safe and effective use of ER/LA opioids. The content is geared toward physicians, physician assistants, nurse practitioners, and others who treat patients with chronic pain. However, dentists rarely (if ever) have to treat chronic pain, much less prescribe an ER/LA opioid.

Dentists are most often faced with managing *acute* pain following dental surgeries (e.g., wisdom tooth extractions, root canals, etc.). For that reason, it would be valuable to have educational content geared toward safely managing *acute* pain, which would include the safe and effective use of immediate-release and short-acting (IR/SA) opioid analgesics.

We recommend that the FDA use its REMS authorities to:

- Require covered drug manufacturers to offer free continuing education that is acceptable for both DEA registration and state licensure purposes.

- Tailor the educational content to the practitioner's scope of practice and the nature of the type of pain managed (e.g., chronic vs. acute pain, dental pain vs. medical pain, etc.).

Further, we urge the FDA to consider using the Prescribers' Clinical Support System for Opioid Therapies (PCSS-O) as a model for offering continuing education through an opioid REMS.

PCSS-O is a web-based prescriber education program funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the American Academy of Addiction Psychiatry (AAAP). Member health care organizations, like the ADA, can leverage PCSS-O resources to help prescribers learn how to manage pain for patients who are at risk for drug overdose and/or addiction.

Since 2012, the ADA has used PCSS-O resources to offer free continuing education webinars on safe and effective opioid prescribing for dental pain. The ADA-produced webinars are free, convenient to access, and tailored to pain management in dentistry. As an incentive, participants are eligible for one hour of continuing education credit for each webinar completed.

The ADA's webinars are administered by a continuing education provider that is approved by the ADA Continuing Education Recognition Program (ADA CERP). The ADA CERP credential provides a sound basis for regulatory agencies to accept the continuing education credit for state licensure purposes.

2. Using its REMS authorities, should FDA require drug companies to require prescribers of their opioid analgesics adhere to additional protocols when prescribing a quantity above a specified amount (e.g., furnishing medical necessity documentation, etc.)? If so, what should the amounts be and how should they be determined for various clinical indications?

The ADA supports statutory limits on opioid dosage and duration of no more than seven days for the treatment of acute pain, consistent with Centers for Disease Control and Prevention (CDC) evidence-based guidelines.

Until the CDC develops a guideline for prescribing opioids for *acute* pain, the ADA recommends that dentists review and follow the relevant portions of the CDC Guideline for Prescribing Opioids for Chronic Pain (2015), which states:

> *"When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."*

3. **Using its REMS authorities, should FDA require covered drug companies to create a national prescription drug monitoring database for real-time identification of doctor shopping and harmful drug combinations?**

The ADA supports dentists registering with and using their *state* prescription drug monitoring program (PDMP) to promote the appropriate use of controlled substances for legitimate medical purposes, while deterring the misuse, abuse and diversion of these substances.

A national PDMP database could be useful if developed and administered properly, especially for prescribers who practice in multiple states.

Considering that every state already has its own unique prescription drug monitoring database—and the registration and reporting requirements are different in each state—we recommend that the FDA focus on coordinating the nation's existing PDMP infrastructure. Doing so would be less expensive and less burdensome than creating an entirely new national system.

We recommend that the FDA use is REMS authorities to:

- Require covered drug companies to enter a cooperative venture to develop effective PDMP quality measures and make state PDMPs interoperable.

4. **Using its REMS authorities, should FDA require covered drug companies to create a vehicle for patients to return unused pills?**

The vast majority of people who abuse prescription opioids get them for free from a friend or relative. Those drugs are often obtained from the home medicine cabinet and sometimes the trash.

The ADA recommends that manufactures and/or pharmacies develop convenient ways for patients to safely secure, monitor and dispose of unused medications. This, coupled with the development of appropriate CDC guidelines for prescribing opioids for acute pain, should significantly reduce the supply of unused opioid medications that can be abused.

The ADA encourages dentists to counsel their patients how to safely secure, monitor and dispose of their unused medications at home.

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